CONSENT FORM

San Francisco State University

Informed consent to participate in the following research study:

Relationship of airborne manganese exposure to neurobehavioral and health status of adults

A. PURPOSE AND BACKGROUND

The researcher of this study, Rosemarie Bowler, Ph.D., is a professor emerita of Psychology at San Francisco State University. The purpose of this study is to determine if there are negative health effects from exposure to airborne manganese and other chemicals in adults. You are being invited to participate in this study because you are a long term resident (10 or more years) of East Liverpool, Ohio and between the ages of 30 and 75. Your participation in this study is completely voluntary.

B. PROCEDURES

If you agree to participate, the following will occur:

- All procedures will take place in our field office in East Liverpool.
- You will be interviewed about your health history. The interview will last approximately 15 minutes.
- You will be asked to complete questionnaires on your medical, social, and psychological history. This will take you about 60 minutes.
- You will be given tests used to measure multiple areas of cognitive functioning, such as general intellectual ability, memory, attention, learning, language, and visual and spatial skills. These tests will take no more than 75 minutes.
- Your motor functioning will be examined with tests of hand strength, balance and tremor, and dexterity. These will take approximately 15 minutes to complete.
- 12 mL (about 2 teaspoons) of blood will be drawn from a vein in your arm by a certified phlebotomist (a person trained to collect blood samples). Your blood will be securely shipped to, stored, and analyzed at the Centers for Disease Control and Prevention (CDC) Environmental Health Laboratory under the direction of the assistant chief of the laboratory, Kathleen Caldwell, Ph.D. Your blood will be analyzed for the following compounds: manganese, lead, mercury, and cadmium, in addition to iron and 2 liver enzymes.
- We will ask you to provide small amounts of your hair (a small sample taken from the back of the head underneath other hair so it will not be noticeable) as well as toenail clippings from all 10 toes. These samples will be analyzed in order to evaluate your exposure to metals.
- Your toenail and hair clippings will be securely shipped to, stored, and analyzed at the Harvard School of Public Health Trace Metals Laboratory. Your toenail clippings will be analyzed for levels of metals.
- Your participation in this study will take an average of 2.5 to 4.0 hours.

C. RISKS

1) When blood is drawn, there is a risk of experiencing slight pain or a prick where the needle punctures the skin. There is also a slight risk of bruising or an infection where the needle punctures the skin. In rare cases, some people may experience lightheadedness, nausea, or fainting. The certified phlebotomist is trained in recognizing and dealing with such reactions. A licensed medical doctor (M.D.) will be on call nearby at all times and will give a consultation in case of a medical emergency for appropriate emergency medical care.

2) Participation in research may involve some possibility of loss of privacy. This risk will be reduced to the extent possible. More information about this risk and how we will reduce it appears in the confidentiality section below.

3) You may feel slight fatigue during testing. Should this occur, you can choose to take a break or discontinue testing at any point.

4) Some of the questions in the questionnaires may be personal and sensitive in nature. You are not required to answer a particular question if you feel uncomfortable.

5) It is possible that results from the blood analysis could reveal serious health problems that you are not aware of. After the analysis, you will be given a report indicating all your test results, and if anything serious is found, you are advised to consult with your family doctor or a local healthcare provider.
6) There may be risks and discomforts that are not yet known.
7) The researchers, research team and sponsors of this project will not provide medical care to participants nor will they cover the cost of medical care for participants.

D. WHAT WILL HAPPEN IF YOU ARE INJURED BY THIS RESEARCH?

All forms of medical research, diagnosis, and treatment involve some risk of injury or illness. Despite our high level of precaution, you may develop an injury or illness due to participating in this study. If you develop an injury or illness determined by the on duty physician to be due to your participation in this research, the EPA will reimburse your medical expenses to treat the injury or illness up to $5000. If you believe your injury or illness was due to a lack of reasonable care or other negligent action, you have the right to pursue legal remedy. The Federal Tort Claims Act, 28 U.S.C. 2671 et. seq., provides for money damages against the United Sates when personal injury or property loss results from the negligent or wrongful act or omission of any employee of the EPA while acting within the scope of his or her employment. Signing this consent form does not waive any of your legal rights or release the investigator, the sponsor, the institution, or its agents from liability for negligence. If a research-related injury occurs, you should contact the Director of the EPA NHEERL Human Research Protocol Office at 919-966-6208 or the Office for the Protection of Human Subjects at San Francisco State University, at 415-338-1093 or protocol@sfsu.edu.

E. CONFIDENTIALITY

Your information will be handled confidentially. Your name will not be used in any published reports about this study. Your results will be entered into a computer database without your name or other identifiers. An ID number will be assigned to all of your test results and only Professor Rosemarie Bowler will be aware of your identity and ID number. The data will be handled only by research staff, all of whom will sign a special confidentiality contract, and will be entered in a password-protected computer database. All research records and test results will be stored in locked file cabinets. All electronic data and results will be kept in an encrypted document on a password-protected computer. Your information will not be released unless subpoenaed by a court of law. All data will be maintained for approximately 5 years in hard copy with access limited to only authorized individuals. The electronic data will be securely stored indefinitely. Unauthorized access will be reported to the relevant parties (participants, stakeholders). Electronic data will be saved on a device that has the appropriate security safeguards (password protection, etc).

F. DIRECT BENEFITS

You will receive the test results in writing, which you can send to your physician. We will indicate whether any results are of concern. If abnormalities are found, you will be referred to your family physician.

G. COSTS

There is no cost to you for participating in this research, aside from the transportation costs of coming to the appointment. Transportation costs involved in come to the field office will not be reimbursed. Medical care will not be provided by the researchers or research team nor will medical care costs be covered.

H. COMPENSATION

You will be presented with a $50 gift card, as a token of appreciation for your participation in the study. Early withdrawal from the study or incompletion of major parts of the study will not be compensated monetarily.

I. ALTERNATIVES

The alternative is not to participate in the research.

J. QUESTIONS

You have spoken with Professor Rosemarie Bowler or one of her collaborators about this study and have had your questions answered. If you have any further questions about the study, you may contact the researcher by email at rbowl@sfsu.edu or by phone at 510-236-5599. Questions about your rights as a study participant, or comments or complaints about the study also may be addressed to the Office for the Protection of Human Subjects at San Francisco State University, at 415-338-1093 or protocol@sfsu.edu.

K. CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN THIS RESEARCH STUDY IS VOLUNTARY. You are free to decline to participate in this research study. You may withdraw from this study at any point without penalty. Even if you sign, you may stop at any time. Your decision to take part in this research will have no influence on your present or future status at San Francisco State University.

Name _____

Signature _____ Date November___, 2011
Participant

Signature _____ Date November 3, 2011
Rosemarie M. Bowler, Ph.D.